Package leaflet: Information for the patient

Alofisel 5 million cells/mL suspension for injection
darvadstrocel

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of Section 4 for how to report side effects.

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or surgeon.
- If you get any side effects, talk to your surgeon or doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Alofisel is and what it is used for

Alofisel is a medicine used for the treatment of complex perianal fistulas in adult patients with Crohn´s disease (a disease causing inflammation of the gut) when the other symptoms of the disease are controlled or have a mild intensity. Perianal fistulas are abnormal channels that connect parts of the lower bowel (rectum and anus) and the skin near the anus, so that one or more openings appear near the anus. Perianal fistulas are described as complex if they have multiple channels and openings, if they penetrate deep inside your body or if they are associated with other complications such as collections of pus (infected liquid also called abscesses). Perianal fistulas can cause pain, irritation and discharge of pus through the openings to the skin.

Alofisel is used when the fistulas have not responded sufficiently well to previous treatment. When injected close to the perianal fistulas, Alofisel reduces their inflammation, increasing the likelihood of the fistulas healing.

Alofisel will be used after adequate preparation of the fistula, see section 3.

The active ingredient of Alofisel is darvadstrocel which consists of stem cells which are taken from the fat tissue of a healthy adult donor (so-called allogenic stem cells) and then grown in a laboratory. Adult stem cells are a special type of cells found in many adult tissues, whose primary role is the repair of the tissue in which they are found.

2. What you need to know before you are given Alofisel

You must not be given Alofisel
- if you are allergic to Alofisel, bovine serum or to any of the ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or surgeon before you are given Alofisel.
Alofisel may contain traces of benzylpenicillin or streptomycin (antibiotics). This should be considered if you are allergic to these antibiotics, as these antibiotics are used in the manufacturing process of this medicine.

Alofisel is a living cell therapy and, therefore, the final product cannot be sterilised. The product is checked at different stages during its manufacture to ensure that it is free of infection. Because the final check takes place just before Alofisel is sent to the hospital, the results of this last check are not known when it is given to you. In the unlikely event that the results detected an infection, your treatment team will be informed who will tell you if you need any laboratory tests of treatment for the infection. If after the procedure you feel ill or have fever, please inform your physician as soon as you can.

Children and adolescents
Do not give this medicine to children and adolescents (i.e. aged under 18 years) because the potential benefits and risks are unknown.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor/surgeon for advice before you are given this medicine. Treatment with Alofisel is not recommended during pregnancy or while breast-feeding. Women of childbearing age should use effective contraception during treatment with Alofisel.

Driving and using machines
Alofisel is not likely to affect your ability to drive or use tools or machines.

Traceability
In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

3. How Alofisel is given

You may have had an initial consultation with the Surgeon 2 to 3 weeks prior to Alofisel administration. The following information is related to the day when Alofisel is administered.

Alofisel is injected by a surgeon in the fistula tract tissue.

The recommended dose is 120 million cells.

Before treatment with Alofisel, you will be given an anaesthetic.

Once you have been anaesthetised (general or regional anaesthesia), your surgeon will:
- clean the fistulas with salt water and remove any scar tissue.
- stitch up the inner openings of the fistulas.
- inject Alofisel. Half of the dose will be injected into the tissue around the inner openings of the fistulas, and half of the dose in the tissue walls along the fistulas.
- massage softly for 20 to 30 seconds the area where the fistula opens on to the skin near your anus.

If you have any further questions on the use of this medicine, ask your doctor or surgeon.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some side effects of Alofisel treatment are related to the process of cleaning your fistulas. In general, these side effects are quite mild and disappear in the days following the fistula procedure.

Common side effects (may affect up to 1 to 10 patients):
- anal abscess
- anal fistula
- proctalgia (pain in the rectum or anus).
- procedural pain (pain after fistula cleaning)

Reporting of side effects
If you get any side effects, talk to your doctor, or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to:

Ireland
HPRA Pharmacovigilance
Website: www.hpra.ie

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Alofisel

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label.

Do not store above 25 °C or below 15 °C.

Do not refrigerate or freeze.

Keep the medicine inside the cardboard box.

Alofisel must not be irradiated or otherwise sterilised.

As this medicine will be used during surgery, the hospital staff is responsible for the correct storage of the medicine before and during its use, as well as for its correct disposal.

6. Contents of the pack and other information

What Alofisel contains
- The active ingredient of Alofisel is darvadstrocel which consists of human stem cells obtained from the fat tissue of a healthy adult donor that are subsequently grown (expanded) in the laboratory and provided at a concentration of 5 million cells per millilitre in vials which each contain 6 millilitres, i.e. 30 million cells per vial.
- There are two excipients used for storage of the cells: one is a liquid called Dulbecco's Modified Eagle´s Medium containing nutrients for the cells (amino acids, vitamins, salts and carbohydrates), and the other is human albumin, which is a natural protein found in the human body.

What Alofisel looks like and contents of the pack

Alofisel is a suspension for injection. During shipment, the cells may have settled in the bottom of the vials forming a sediment and will need to be resuspended. After the cells have been resuspended (by gentle manual tapping), Alofisel is a white to yellowish homogenous suspension.
Alofisel is supplied on an individual patient basis. An individual dose of Alofisel comprises 4 glass vials each containing 6 millilitres of Alofisel contained within a cardboard box.

Marketing Authorisation Holder

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Other sources of information
Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europe.eu.

The following information is intended for healthcare professionals only:

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